



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-0199]

Enforcement Policy on National Health Related Item Code and National Drug Code Numbers

Assigned to Devices; Guidance for Industry and Food and Drug Administration Staff;

Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled "Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices." This guidance describes the Agency's intent not to enforce the prohibition against providing National Health Related Item Code (NHRIC) or National Drug Code (NDC) numbers on device labels and device packages, with respect to finished devices that are manufactured and labeled prior to September 24, 2021. In addition, this guidance describes the Agency's intent to continue considering requests for continued use of FDA labeler codes under a system for the issuance of unique device identifiers (UDIs) that are submitted before September 24, 2021.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-D-0199 for "Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices; Guidance for Industry and Food and Drug Administration Staff." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, rm. 3303, Silver Spring, MD 20993-0002, 301-796-5995, [GUDIDSupport@fda.hhs.gov](mailto:GUDIDSupport@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the Federal Register of February 3, 2016, FDA announced the availability of "Draft Guidance for Industry and Food and Drug Administration Staff: Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices" (81 FR 5760) (the "Draft Guidance"). The Draft Guidance described FDA's intent not to enforce

before September 24, 2021, the prohibition against providing NHRIC and NDC numbers on device labels and device packages of certain devices that are manufactured and labeled prior to September 24, 2018. Interested persons were invited to comment by April 4, 2016.

FDA received 13 sets of comments on the Draft Guidance, the majority of which commented that stakeholders, including supply chain participants, pharmacies, and payers, would not be able to complete the work to transition away from use of NHRIC and NDC numbers by September 24, 2018. Some commenters also expressed concern that after September 24, 2021, retailers and pharmacies would need to send some devices with shelf lives exceeding 3 years, and with NHRIC or NDC numbers on their labels or device packages, back to the device labelers.

FDA has revised the guidance to reflect the Agency's intent not to enforce the prohibition against providing NHRIC and NDC numbers on device labels and device packages, with respect to finished devices that are manufactured and labeled prior to September 24, 2021. We expect the UDI labeling requirements will be fully implemented by September 24, 2021. We also believe additional time is appropriate for stakeholders to adopt medical device reimbursement, supply chain, and procurement systems, which do not depend on having an NHRIC or NDC number on the device label.

## II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices". It does not establish any rights for any person and is not binding on FDA or the public. You can

use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

### III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy of "Enforcement Policy on National Health Related Item Code and National Drug Code Numbers Assigned to Devices" may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number GUD1500044 to identify the guidance you are requesting.

### IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 801, subparts A and B have been approved under OMB control number 0910-0720.

Dated: August 24, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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